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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,676	08/19/2003	Terry Thomas	A35897-PCT-USA-A (072667.	4695

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,676	THOMAS ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 19, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0104*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are currently amended in the amendment filed August 19, 2003.

Claims 12-23 are newly added in the amendment filed August 19, 2003.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The abstract of the disclosure is objected to because line 1 recites "and" where it appears "an" was intended. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid comprising SEQ ID NO:1. The claims are also drawn to an isolated nucleic acid comprising a fragment of SEQ ID NO:1 wherein said fragment has promoter activity. The claims are additionally drawn to an isolated nucleic acid having at least 70% sequence identity to SEQ ID NO:1 wherein said nucleic acid has promoter activity. The claims are further drawn to an isolated nucleic acid having promoter activity wherein said nucleic acid hybridizes to SEQ ID NO:1 under high stringency conditions. The claims are also drawn to a nucleic acid construct comprising said promoters operably linked to a heterologous nucleic acid, and to a vector, a transgenic plant cell and a transgenic plant comprising said promoters.

The specification describes SEQ ID NO:1 as a 2030 bp nucleotide sequence obtained from *Arabidopsis* (sequence listing).The specification describes SEQ ID NO:2 as a 2042 bp nucleotide sequence obtained from *Arabidopsis* (sequence listing). The specification also describes SEQ ID NO:2 as being obtained by the amplification of a putative promoter region located upstream of the putative translation start site of an endomembrane-associated protein contained in an *Arabidopsis* BAC clone designated F1C12 and deposited in GenBank as Accession No. AL022224, and as depicting the amplified product and containing artificial restriction sites introduced during PCR to facilitate cloning (page 13). The specification additionally describes SEQ ID NO:2 as driving the expression of an operatively linked GUS reporter gene in most tissues of transgenic Arabidopsis plants transformed therewith (pages 13-14). The search of SEQ ID NO:1 indicates that nucleotides 7 to 2036 of SEQ ID NO:2 correspond to nucleotides 1 to 2030 of SEQ ID NO:1. The specification does not describe

variants promoter sequences that have at least 70% sequence identity to SEQ ID NO:1, or that hybridize to SEQ ID NO:1 under high stringency conditions.

The Federal Circuit has recently clarified the application of the written description requirement to nucleic acid sequences. The court stated that "A description of a genus of cDNAs may be achieved by means of recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1569; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

In the instant case Applicant has not described a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized variants of SEQ ID NO:1, nor the structural features unique to the genus that are correlated with the variant's promoter activity.

Claims 2-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:2, does not reasonably provide enablement for other isolated nucleic acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or the invention commensurate in scope with these claims.

The claims are drawn to an isolated nucleic acid comprising SEQ ID NO:1. The claims are also drawn to an isolated nucleic acid comprising a fragment of SEQ ID NO:1 wherein said fragment has promoter activity. The claims are additionally drawn to an isolated nucleic acid

having at least 70% sequence identity to SEQ ID NO:1 wherein said nucleic acid has promoter activity. The claims are further drawn to an isolated nucleic acid having promoter activity wherein said nucleic acid hybridizes to SEQ ID NO:1 under high stringency conditions. The claims are also drawn to a nucleic acid construct comprising said promoters operably linked to a heterologous nucleic acid, and to a vector, a transgenic plant cell and a transgenic plant comprising said promoters.

The specification discloses the cloning of SEQ ID NO:2 from *Arabidopsis* by the amplification of a putative promoter region located upstream of the putative translation start site of an endomembrane-associated protein contained in an *Arabidopsis* BAC clone designated F1C12 and deposited in GenBank as Accession No. AL022224 (page 13). The specification additionally discloses the use of SEQ ID NO:2 to drive the expression of an operatively linked GUS reporter gene in most tissues of transgenic Arabidopsis plants transformed therewith (pages 13-14). The search of SEQ ID NO:1 indicates that nucleotides 7 to 2036 of SEQ ID NO:2 correspond to nucleotides 1 to 2030 of SEQ ID NO:1. The specification does not disclose promoters that are functional fragments of SEQ ID NO:1, or variants promoter sequences that have at least 70% sequence identity to SEQ ID NO:1, or that hybridize to SEQ ID NO:1 under high stringency conditions.

The full scope of the claimed invention is not enabled because it is unpredictable whether fragments or variants of SEQ ID NO:1 would retain promoter function, because promoter function requires the presence of specific nucleotides and nucleotide sequence motifs in the nucleic acid sequence, which nucleotides and motifs may not be present in fragments or variants of SEQ ID NO:1.

See, for example, Kim Y.et al. (A 20 nucleotide upstream element is essential for the nopaline synthase (nos) promoter activity. Plant Mol Biol. 1994 Jan;24(1):105-17), who teach that various point mutations in the nos promoter can alter the level of promoter activity in tobacco. Mutation of one or more key nucleotides in either of two hexamer motifs or in the octamer spacer region between them significantly altered the level of *nos* promoter activity (Table 2, page 109). A single point mutation in the sixth nucleotide of the hexamer motif resulted in a four to ten fold decrease in promoter activity, whereas a double point mutation in the fourth and fifth nucleotide of the hexamer motif resulted in a two-fold increase in promoter activity. Two independent triple point mutations in the third, fourth and fifth, and sixth, seventh and eighth nucleotides of the octamer spacer region eliminated detectable promoter activity.

In the instant case Applicant has not provided guidance with respect to the identity and location of key nucleotides and motifs required for promoter function that would be retained by fragments and variants of SEQ ID NO:1. Absent such guidance it would one skilled in the art would have to isolate from undisclosed sources and/or synthesize numerous fragments and variant sequences, and then test each sequence for its ability to function as a promoter sequence, in order to discriminate between operative and inoperative embodiments encompassed by the claims. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Bevan M. et al. (GenBank Accession No. AL022224, September 20, 1999, Arabidopsis thaliana DNA chromosome 4, BAC clone F1C12).

The claims are drawn to an isolated nucleic acid comprising SEQ ID NO:1. The claims are also drawn to an isolated nucleic acid comprising a fragment of SEQ ID NO:1 wherein said fragment has promoter activity. The claims are additionally drawn to an isolated nucleic acid having at least 70% sequence identity to SEQ ID NO:1 wherein said nucleic acid has promoter activity. The claims are further drawn to an isolated nucleic acid having promoter activity wherein said nucleic acid hybridizes to SEQ ID NO:1 under high stringency conditions. The claims are also drawn to a vector comprising said promoters.

Bevan M. et al. teach an isolated nucleic acid comprising SEQ ID NO:1. The isolated nucleic acid taught by Bevan M. et al. inherently comprises functional fragments SEQ ID NO:1, has 100% sequence identity to SEQ ID NO:1 and would hybridizes to SEQ ID NO:1 under high stringency conditions. The BAC clone comprising the isolated nucleic acid taught by Bevan M. et al. is a vector.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

Cynthia Collins
10/31/05